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Registration Decision RD2011-02

Chlorantraniliprole

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Registration Decision for Chlorantraniliprole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Rynaxypyr Technical Insecticide and the end-use products, DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Acelepryn Insecticide, containing the technical grade active ingredient chlorantraniliprole, to control a variety of insect pests in several agricultural crops and turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-27, *Chlorantraniliprole*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for chlorantraniliprole and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-27, *Chlorantraniliprole*. This decision is consistent with the proposed registration decision stated in PRD2010-27, *Chlorantraniliprole*.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-27, *Chlorantraniliprole* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Chlorantraniliprole?

Chlorantraniliprole is an agricultural insecticide to be applied as a foliar application to control a variety of insect pests in several agricultural crops and turf. Currently, chlorantraniliprole is the only insecticide registered in Canada with this particular mode of action. It kills insects by overstimulating their muscles.

Health Considerations

Can Approved Uses of Chlorantraniliprole Affect Human Health?

Chlorantraniliprole is unlikely to affect your health when used according to label directions.

Exposure to chlorantraniliprole may occur through diet (food and water), when handling and applying the product, or through contact with residues on turf. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when using chlorantraniliprole products according to label directions.

The technical grade active ingredient chlorantraniliprole and its end-use products, DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Acelepryn Insecticide, are of low acute toxicity to animals after a single dose, are non-irritating to the skin and eyes, and do not cause an allergic skin reaction. Chlorantraniliprole did not cause cancer in animals and does not damage genetic material, such as DNA. There was no indication that chlorantraniliprole affects the immune or endocrine system, and there was no evidence that it causes damage to the nervous system in rats. When chlorantraniliprole was given to pregnant animals, there was no evidence that it affects the developing fetus.

The first signs of toxicity in animals given daily doses of chlorantraniliprole over longer periods of time were adaptive effects on the liver. At high doses, however, male mice did show signs of liver effects that were considered adverse. In some studies, the adrenal gland of male rats changed in appearance due to a slight increase in the amount of lipid droplets following exposure to chlorantraniliprole. However, this was not considered toxicologically significant.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that children 1 to 2 years old, the population group that would ingest the most chlorantraniliprole relative to body weight, are expected to be exposed to <1.3% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from chlorantraniliprole is not of concern for any segment of the population. Chlorantraniliprole is not carcinogenic; therefore, a chronic cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of chlorantraniliprole is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using chlorantraniliprole on apple, pear, peach, plum, sweet and sour cherries, grapes, broccoli/cauliflower, cabbage, mustard greens, cucumber, cantaloupe/muskmelon, summer squash, tomato, bell and non-bell peppers, head/leaf lettuce, celery, spinach, potato and cotton were acceptable. The MRLs for this active ingredient can be found in Evaluation Report ERC2008-03, *Chlorantraniliprole*.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern when DuPont Coragen Insecticide or DuPont Acelepryn Insecticide is used according to the proposed label directions.

Individuals entering recreational areas, such as golf courses and parks, or home and residential lawns treated with DuPont Coragen Insecticide and DuPont Acelepryn Insecticide, can come in contact with foliar residues of chlorantraniliprole. However, subsequent risk to these individuals is considered negligible.

Occupational Risks From Handling DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Acelepryn Insecticide

Occupational risks are not of concern when DuPont Altacor Insecticide, DuPont Coragen Insecticide or DuPont Acelepryn Insecticide is used according to the proposed label directions, which include protective measures.

Farmers and pesticide applicators mixing, loading or applying DuPont Altacor Insecticide, DuPont Coragen Insecticide or DuPont Acelepryn Insecticide, as well as field workers reentering freshly treated fields, can come in direct contact with chlorantraniliprole on the skin or through inhalation of spray mists. Therefore, the labels specify that anyone mixing, loading or applying DuPont Altacor Insecticide, DuPont Coragen Insecticide or DuPont Acelepryn Insecticide must wear a long-sleeved shirt, long pants and chemical-resistant gloves. Taking into consideration these label requirements, risk to farmers, applicators or field workers is not a concern.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Chlorantraniliprole Is Introduced Into the Environment?

Chlorantraniliprole enters the environment when used on various crops and turf for control of various insects. Although the use pattern of chlorantraniliprole does not include direct application to water, it can enter the aquatic environment through spray drift and runoff from treated fields. Chlorantraniliprole residues are not expected in the air because of its low volatility.

Chlorantraniliprole is persistent and mobile in soil and moderately persistent in the aquatic environment. The major breakdown product, (2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethyl-4(3H)-quinazolinone (IN-EQW78) is more persistent than chlorantraniliprole in the soil and aquatic environment. Chlorantraniliprole is expected to leach through the soil profile beyond 60 cm, therefore, it is expected to reach groundwater. In surface waters, chlorantraniliprole will partition to sediment and is expected to accumulate in aquatic systems. A Canadian field dissipation study in Prince Edward Island demonstrated that up to approximately 48% of applied chlorantraniliprole is expected to carry over to the following growing season.

The risk to the environment was assessed for chlorantraniliprole and the end-use products DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Acelepryn Insecticide. Use of chlorantraniliprole according to approved product labels is not expected to present any risk to wild mammals, birds, earthworms, terrestrial plants, bees, fish, algae and aquatic plants. However, risks to some non-target terrestrial arthropods and aquatic invertebrates have been identified.

Value Considerations

What Is the Value of DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Accelepryn Insecticide?

DuPont Altacor Insecticide (35% chlorantraniliprole) is registered for the control of a variety of insect pests in pome fruits, stone fruits and grapes. DuPont Coragen Insecticide (200 g/L chlorantraniliprole) is registered to control many insect pests in potatoes, fruiting vegetables, *Brassica* vegetables, leafy vegetables and in turf. The control of several insect pests in turf is also supported on the DuPont Accelepryn Insecticide (200 g/L chlorantraniliprole) label.

Currently, chlorantraniliprole is the only insecticide registered in Canada with the ryanodine receptor modulator mode of action. Chlorantraniliprole represents another mode of action that can be used to control listed pests on pome fruits, stone fruits, grapes, potatoes, fruiting vegetables, *Brassica* vegetables, leafy vegetables and turf. This is important for integrated pest management and for resistance management strategies.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Accelepryn Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As users may come into direct contact with chlorantraniliprole on the skin or through inhalation of spray mists, anyone mixing, loading or applying DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Accelepryn Insecticide must wear a long-sleeved shirt, long pants and chemical-resistant gloves.

Because individuals can come into contact with treated foliage when re-entering treated residential areas, re-entry into treated areas is restricted for 12 hours after application.

Environment

To address the concerns related to carryover, runoff, leaching, and risk to non-target arthropods, environmental hazard label statements are required for DuPont Altacor Insecticide, DuPont Coragen Insecticide and DuPont Acelepryn Insecticide. To protect aquatic organisms, spray buffer zones of one to ten metres are required for ground applications and one to fifteen metres for aerial applications. The distance allowed depends on the type of spray equipment used and the timing of application.

Other Information

The relevant test data on which the decision is based (as referenced in Evaluation Report ERC2008-03, *Chlorantraniliprole* and PRD2010-27, *Chlorantraniliprole*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.